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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,434

Applicant(s)

SHEEN ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The numbering of claims 12-15 is not in accordance with 37 CFR 1.126 because the claim numbering is not in consecutive order. Misnumbered claims 12-15 have been renumbered 11-14. Claim dependency has been corrected. All future correspondence should refer to the new numbers. Claims 1-14 are pending and are examined.

Priority

The status of the parent application 09/371, 338 on page 1 of the specification should be updated.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the sequences of Figure 11 have not been identified by SEQ ID NO: in the Brief Description of the Drawings on page 18 of the specification. Applicant is respectfully requested to identify the sequence presented in the figure or to submit a new Sequence Listing which comprises said sequence.

Claim Objections

At claims 8 and 9, "a plant" should be replaced with ---the plant--- because it refers to a previous claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "capable" which implies the transgene may or may not express a MAPKKK or kinase domain thereof. It is unclear under what conditions the transgene may express the kinase. In addition, it is unclear as to whether the promoter recited in the claim is in addition to the promoter already present in the transgene. Clarification is required to more clearly define the metes and bounds of the claims. It is suggested that "transgene capable of expressing" be replaced with ---nucleic acid encoding---;

The word "transgene" in claims 1 and 2 implies the presence of coding and non-coding regulatory regions including a promoter. Dependent claims 3-9 are included in the rejection. It is suggested that "transgene in line 3 of claim 1 and in claim 2 be replaced with ---nucleic acid---.

Claims 10 and 11 are indefinite because it is unclear as to whether the promoter is in addition to the promoter already present in the gene encoding MAPKKK. The word "gene" implies the presence of coding and non-coding regulatory regions including a promoter. Dependent claims 12-14 are included in the rejection. It is suggested that "transgene" in claim 10 and "gene" in claim 11 be replaced with ---nucleic acid---.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. The claims do not read, "transgenic" seed or cell, and therefore the claim reads on the product of nature. Due to chimerism, not all of the cells from a transgenic plant will comprise in their genome the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed seed/cell, it is unclear whether the claimed seed/cell would be distinguishable from seed/cell that would occur in nature. See *Diamond v. Chakrabarty* 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. An Amendment to the claims to insert ----transgenic--- before, "A" in claims 8 and 9 would obviate the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-10, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanksley et al (US 5, 648, 599, Applicant's IDS).

The claims are directed to a plant comprising a recombinant transgene capable of expressing a kinase domain of a mitogen-activated protein kinase kinase kinase (MAPKKK) "or a kinase domain thereof" from a plant, wherein said transgene is expressed under the control of a promoter functional in a plant cell. The claims are also

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drawn to a vector comprising a promoter operably linked to said transgene, and a plant cell comprising the vector.

Tanksley et al teach monocot or dicot plant transformed with a transgene encoding a plant serine/threonine kinase operably linked to a promoter functional in plant cells, wherein the transformed plants express the kinase. The cited reference teaches a vector comprising said transgene, and a plant cell comprising said vector (columns 17-20, and claims 11-21). The claimed transgenic plant and plants cells, and vector comprising a transgene encoding a kinase domain of a MAPKKK appear to be similar to the transgenic plant and plant cells and vector comprising a plant serine/threonine kinase of the prior art , absent evidence to the contrary. Therefore, Tanksley et al teach all claims limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanksley et al (US 5, 684, 599, Applicant's IDS) in view of Mizoguchi et al (PNAS, Vol. 93, pp. 765-769 (1996), Applicant's IDS).

Tanksley et al teach monocot or dicot plant transformed with a transgene encoding a plant serine/threonine kinase operably linked to a promoter functional in plant cells, wherein the transformed plant expresses the kinase as discussed above.

Tanksley et al do not explicitly teach a transgene encoding a kinase from animal or fungi or MAPKKK in a transgenic plant or cell or vector.

Mizoguchi et al teach a gene encoding MAPKKK from plant, yeast and mouse (see at least the Abstract on page 765). On Page 765, column 1, 2nd full paragraph, the cited reference teaches isolation and characterization of MAPKKK encoding genes, and their roles in signal transduction pathways in plants under environmental stresses.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to transform a plant with a gene encoding a kinase protein for a desired trait as taught by Tanksley et al, and to modify that method by incorporating any other known kinase encoding gene including an MAPKKK encoding gene taught by Mizoguchi. One having ordinary skill in the art would have been motivated to do this, given the availability of MAPKKK encoding genes and their roles in signal transduction pathway under stress conditions as taught by Mizoguchi et al. The claims fail to recite specific structural characteristics (such as percent of identity) that would distinguish the

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claimed transgene from the prior art gene. Therefore, the claimed invention as whole was clearly a prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. US 6,613,959. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the application are directed to a transformed plant/seed/cell comprising a recombinant transgene encoding any plant/fungi/animal MAPKKK or kinase domain thereof under the control of a promoter functional in plant cells, and the claims in the issued patent are drawn to a method for producing a transformed plant/seed/cell comprising specified nucleic acid sequence encoding a plant MAPKKK under the control of a specific promoter functional in plant cells. The claims in the application are broader in scope, and therefore encompass the invention claimed in the patent. Therefore, it would have obvious to one of ordinary skill

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in the art to transform a plant with a gene encoding a MAPKKK or kinase domain thereof for a reasonable expectation of success. Therefore, the rejection is proper.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mai

2/7/05

Medina A. Ibrahim

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MEDINA A. IBRAHIM
PATENT EXAMINER